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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,593	10/31/2005	Motoyuki Ashikari	SHZ-024US	7806
			EXAM	INER
ONE POST OF	10/534,593 10/31/2005 Motoyuki Ashikari		BUI, PHUONG T	
BOSTON, MA	02109-2127	·	ART UNIT	PAPER NUMBER
			1638	
			MAIL DATE	DELIVERY MODE
			11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<u> </u>		Application No.	Applicant(s)			
Office Action Summary		10/534,593	ASHIKARI ET AL.			
		Examiner	Art Unit			
		Phuong T. Bui	1638			
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the c	orrespondence address			
A SH WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANS IN THE MAIL	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status		,				
1)🛛	Responsive to communication(s) filed on 18 Se	eptember 2007.				
2a)⊠	This action is <b>FINAL</b> . 2b) This action is non-final.					
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	i3 O.G. 213.			
Dispositi	on of Claims					
5)□ 6)⊠ 7)□	Claim(s) 1-19 is/are pending in the application.  4a) Of the above claim(s) 4,5,13-15,17 and 19 i Claim(s) is/are allowed.  Claim(s) 1-3,6-12,16 and 18 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or	is/are withdrawn from considerati	on.			
Applicati	on Papers					
10)□	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correcti The oath or declaration is objected to by the Example.	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority u	ınder 35 U.S.C. § 119					
a)[	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the prioric application from the International Bureausee the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been receive (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment	(s)					
1) 🔀 Notice 2) 🔲 Notice 3) 🔯 Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) ' No(s)/Mail Date 6/5/07.	4) Interview Summary ( Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other:				

### **DETAILED ACTION**

1. The Office acknowledges the receipt of Applicant's amendment filed September 18, 2007. Claims 1-19 are pending. Claims 4, 5, 13-15, 17 and 19 are nonelected.

Claims 1-3, 6-12, 16 and 18 are examined in the instant application. All previous rejections not addressed below have been withdrawn.

Since SEQ ID NOs:1, 2 and 3 were not disclosed in provisional application 60/425919, Applicant shall have priority benefit of PCT/JP03/14434 filed November 13, 2003.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL.

#### Information Disclosure Statement

2. An initialed and signed copy of Applicant's IDS filed June 5, 2007 is attached to the instant Office action.

# Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph

3. Claims 1-3, 6-12, 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1(b), "a coding region" should be amended to "the coding region" because SEQ ID NO:1 has only one coding region.

In claim 1(d) "sequence" should be inserted after "95%" to indicate that comparison of sequences is based on the sequences themselves and not on function or other parameters.

In claim 16, the recitation of "or a fully complementary sequence thereof" is unclear. Does Applicant intend to claim the complement of the 15 nucleotides or the full-length complement of SEQ ID NOs:1 and 2?

Clarification and/or correction is required.

# Claim Rejections - 35 USC § 112, 1st paragraph, written description

4. Claims 1-3, 6-12, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines.

The recitation of 95% identity lacks adequate written description because Applicant does not disclose a representative number of species as encompassed by these claims. The claims encompass other genes and their mutants and their allelic variants, yet no other genes or structural variants have been disclosed. The claims also encompass protein sequences other than cytokinin oxidase (CKX) from other species, as the claims are not limited by any recited function. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known. Applicant discloses SEQ ID NO:1 (its cDNA is SEQ ID NO:2) isolated from rice whereby deletion of its function increases flowers, fruits or seeds in a

plant. Thus, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine other gene sequences, their mutants and allelic variants, and sequences from other plants and organisms whereby its deletion of function also increases flowers, fruits or seeds in a plant, absent further guidance. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time of filing. Thus, for the reasons set forth above, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111).

Applicant traverses, stating that Example 14 of the Written Description

Guidelines indicates that 95% sequence identity and having a particularly specified catalytic activity satisfies the requirements for written description.

Applicant's traversal has been considered but is deemed unpersuasive because whether or not a claimed invention has adequate written description is fact specific. How many species are disclosed or known within the claimed genus at the time of filing is an important factor in determining whether or not a claimed invention is adequately described. The greater the number of species disclosed, the more predictable it is for one skilled in the art to determine other sequences within the claimed genus. The only other CKX sequence disclosed is from *Arabidopsis*. The Office does not consider two species to adequately represent the genus claimed. Furthermore, no catalytic activity is recited, as "glumous flowers, fruits or seeds" is a plant phenotype due to deletion of

function. It is not a gene function or activity. "Cytokinin oxidase activity" would be a catalytic activity. Accordingly, the claimed invention lacks adequate written description.

## Claim Rejections - 35 USC § 112, enablement

4. Claims 1-3, 6-12, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:1, 2 or DNA encoding SEQ ID NO:3, does not reasonably provide enablement for sequences having 95% sequence identity to a sequence encoding SEQ ID NO:3 or "an agent for changing the number of flowers, fruits or seeds" of a plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The 95% identity language encompasses unspecified substitutions, deletions, additions, insertions, and their combinations thereof. No function is recited. The recitation of "deletion of function...results in an increase in the glumous flowers, fruits, or seeds of a plant" indicates a phenotype when the gene is deleted, and does not allow one skilled in the art to determine which sequences within the 95% identity scope would have the same function as SEQ ID NO:3. Applicant provided no working example of sequences having 95% identity to the disclosed sequence. Applicant has not shown that any sequence within the 95% identity would retain the function of the full-length sequence of SEQ ID NO:3. It is unlikely that the function of the protein—cytokinin oxidase—would be retained with any mutation within the 95% scope. It is unclear how the 95% identity having the same function can be determined when the only way to determine the claimed sequence is by deleting its function. It would appear that the

claims encompass sequences having cytokinin oxidase activity even though no activity is recited. However, Applicant provided no guidance as to what mutations would be tolerated. While one skilled in the art can readily make mutations to the disclosed sequences, further guidance is needed as to what mutations would not abrogate enzyme activity.

With regard to claim 18, the breadth of "changing the number of glumous flowers, fruits, or seeds of a plant" encompasses both increase and decrease. However, Applicant provided no guidance or working example as to how to decrease using the same sequences. One skilled in the art would not know how to decrease glumous flowers, fruits, or seeds of a plant based upon Applicant's disclosure. Furthermore, there is no evidence that adding or having SEQ ID NO:1 or 2 in a plant (the opposite of deletion of function) would decrease the particle bearing number, since rice naturally contains SEQ ID NO:1 encoding SEQ ID NO:2.

Given the breadth of the claims and lack of guidance, working examples, or a functional recitation, one skilled in the art cannot make and use the claimed invention as commensurate in scope with the claims without undue experimentation.

Applicant traverses that the enablement training materials indicates that if there is at least one working embodiment within the scope of the claimed invention, then the claimed invention is enabled. Applicant further traverses that the Office deemed a single disclosed species to be representative of the clamed genus which would hybridize under highly stringent conditions.

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Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. The instant rejection is not a complete lack of enablement but a scope of enablement. Thus, Applicant's first traversal does not apply here. There is at least one enabling embodiment. Applicant's second traversal addresses the written description issue rather than enablement, and thus would also not apply here. The written description rejection has been discussed above. Further, none of the claims recites hybridization language as argued. Applicant did not address or amend the scope of claim 18. Accordingly, this rejection is maintained.

## Claim Rejections - 35 USC § 102

- 5. Claims 1-3, 6-12, 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al. (WO2003000898, filing date June 22, 2001 (N)). Chang teaches a rice sequence of SEQ ID NO: 3500 which encodes a protein having 99.5% sequence identity to Applicant's SEQ ID NO:3. The deletion of function resulting in an increase in glumous flowers, fruits or seeds would be an inherent property of the sequence of Chang. The DNA of Chang would encode an RNA fully complementary to a transcript of the DNA. Chang also teaches vector, host plant cell, plant, seed, and method for producing a transformed plant. Accordingly, Chang anticipated the claimed invention.
- 6. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Boukharov (US 2007/0020621, filing date March 23, 2001, previously cited). Boukharov teaches a sequence of SEQ ID NO:68122 which has 100% sequence identity to SEQ ID NO:1. Accordingly, the claimed invention is anticipated by the prior art.

Applicant traversed that the claims have been amended to consist of only the coding region of SEQ ID NO:1.

Applicant's traversal is unpersuasive because claim 18 is not limited to the coding region of SEQ ID NO:1 but any 15-mer of SEQ ID NO:1.

Accordingly, this rejection is being maintained

#### Conclusion

- 7. No claim is allowed.
- 8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communications from the Examiner should be directed to Phuong Bui, whose telephone number 571-272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned, for sending official correspondence, is 571-273-8300.

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Phuong T. Bui Primary Examiner Art Unit 1638

11/6/07